GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3295
ANSWERED ON:06.12.2016
Generic Drug Sale
Sundaram Shri P.R.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Pharmaceutical sector is suffering due to too much counter sale of generic drugs and medicines by drug stores and medical shops;

(b) if so, the details thereof and the corrective steps taken by the Government in this regard;

(c) the modalities, guidelines and norms chalked out by the Government to check, monitor and curb the distribution and sale of spurious drugs and expired medicines in the country; and

(d) the total quantum and value of spurious drugs and expired medicines found/detected from the pharmaceutical market across the country during the last three years and the current year?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): No, Madam. As per the report of Working Group on Drugs and Pharmaceutical Industry 12th Five Year Plan (2012-2017), the Indian Pharmaceutical Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production.

(c): The Govt. of India has taken/taking the following steps to improve the quality of drugs in the country:-

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable by setting of special Courts.

2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

3. A Whistle Blower Scheme was announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs. The details of policy are available at the website of CDSCO (www.cdsco.nic.in).

4. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

5. The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

6. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 474 in 2016.

7. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

(d): Isolated cases of spurious and expired drugs have been detected in the country. The State/UT-wise data on spurious drugs found to be detected in the country during last three years and current year, as per information received from various State/U.T. Drugs Controllers is enclosed as Annexure-A.

Such data in respect of expired drugs is enclosed as Annexure-B.

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2013- March 2014

S.No. States No. of drugs samples declared not of standard quality No. of drugs samples declared spurious/ adulterated Approx. value of drug seized (Rs.)
1 Andhra Pradesh 61 12 134.68 lakhs
2 Arunachal Pradesh 6 Nil NA
3 Assam 39 Nil Nil
4 Bihar 52 4 50,000
5 Goa 34 Nil Nil
6 Gujarat 567 32 Nil
7 Haryana 52 3 Apprx. 2Lakh
Himachal Pradesh 28 1 NA
9 Jammu & Kashmir 153 6 (03-spurious, 03- Adultrated) 9969962
10 Karnataka 292 4 Nil
11 Kerala 152 Nil Nil
12 Madhya Pradesh 75 Nil Nil
13 Maharashtra 466 19 37.85 lakhs
14 Manipur Nil Nil Nil
15 Meghalaya 1 Nil Nil
16 Mizoram Nil Nil 12 lakhs
17 Nagaland 4 Nil Nil
18 Orissa 74 2 59775
19 Punjab 106 3 7566079
20 Rajasthan 38 7 1318489
21 Sikkim Nil Nil Nil
22 Tamilnadu 314 6 13256
23 Tripura 35 2 Nil
24 Uttar Pradesh 336 5 4536820
25 West Bengal 22 Nil 300000
26 Pondicherry Nil Nil Nil
27 Andaman & Nicobar Nil Nil Nil
28 Chandigarh 3 None None
29 Delhi 17 5 NA
30 Dadra & Nagar Haveli Nil Nil Nil
31 Daman & Diu Nil Nil Nil
32 Lakshadweep Nil Nil Nil
33 Chattisgarh 11 Nil Nil
34 Jharkhand 59 Nil Nil
35 Uttarakhand 31 7 Not Yet calculated
Total 3028 118 424.67 lacs

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2014- March 2015
S.No. States No. of drugs samples declared not of standard quality No. of drugs samples declared spurious/ adulterated Approx. value of drug seized (Rs.)
1 Andhra Pradesh 10 4 1010635
2 Arunachal Pradesh 7 1 (Misbranded) Nil
3 Assam 39 Nil Nil
4 Bihar* 11 Nil Nil
5 Goa 11 Nil Nil
6 Gujarat 499 5 Nil
7 Haryana 25 2 Nil
Himachal Pradesh 31 Nil NA
9 Jammu & Kashmir 42 1 1,865,950
10 Karnataka 302 â€¦. 527095
11 Kerala 103 Nil Nil
12 Madhya Pradesh 27 1 Nil
13 Maharashtra 420 25 35006352
14 Manipur Nil Nil Nil
15 Meghalaya 1 Nil Nil
16 Mizoram Nil Nil Nil
17 Nagaland Nil Nil Nil
18 Orissa 98 1 97,240
19 Punjab 61 8 2218274
20 Rajasthan 97 3 2929097
21 Sikkim 1 Nil Nil
22 Tamilnadu 387 2 Nil
23 Tripura 22 Nil Nil
24 Uttar Pradesh 1384 28 4833868
25 West Bengal 22 1 Nil

26 Pondicherry Nil Nil Nil
27 Andaman & Nicobar Nil Nil Nil
28 Chandigarh 3 None 183000
29 Delhi 1 1 19000
30 Dadra & Nagar Haveli Nil Nil Nil
31 Daman & Diu Nil Nil Nil
32 Lakshadweep Nil Nil Nil
33 Chattisgarh 24 Nil Nil
34 Jharkhand 29 Nil 140000
35 Uttarakhand 10 Nil Nil
36 Telangana 35 Nil 94,20,600(in the month of April
Total 3702 83 58251111

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during 1st April 2016 to 30th September 2016

S.No. States No. of drugs samples declared not of standard quality No. of drugs samples declared spurious/ adulterated Approx. value of drug seized
1 Andhra Pradesh 17 Nil 10470763
2 Arunachal Pradesh 19 4 (Spurious 3 + misbranded 1) NA
3 Assam 8 Nil Nil
4 Bihar 11 Nil 26311817
5 Goa 10 Nil Nil
6 Gujarat 208 5 Nil
7 Haryana 8 2 25583.12
8 Himachal Pradesh 18 5 Nil
9 Jammu & Kashmir 23 Nil Nil
10 Karnataka 219 Nil 97,937
11 Kerala 66 Nil Nil
12 Madhya Pradesh
13 Maharashtra
14 Manipur Nil Nil Nil
15 Meghalaya Nil Nil Nil
16 Mizoram 4 Nil Nil
17 Nagaland Nil Nil Nil
18 Orissa 54 Nil Nil
19 Punjab 28 11 1,699,200
20 Rajasthan 62 9 199428.00
21 Sikkim 3 Nil Nil
22 Tamilnadu 235 1 Nil
23 Tripura 3 Nil Nil
24 Uttar Pradesh 423 (Sub-std.-113+
Misbranded-310) 3 5302948/-
25 West Bengal 20 Nil Nil
26 Pondicherry Nil Nil Nil
27 Andaman & Nicobar Nil Nil Nil
28 Chandigarh 1 Nil Price of four portions seized on form 17 Rs. 622/- of drugs declared as not of standard quality
29 Delhi 6 Nil 15000
30 Dadra & Nagar Haveli Nil Nil Nil
31 Daman & Diu
32 Lakshadweep Nil Nil Nil
33 Chattisgarh Nil Nil Nil
34 Jharkhand 2 Nil -
35 Uttarakhand 20 Nil Nil
36 Telangana 19 Nil Nil
Total 1487 40 4,41,23,298.12

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2015- March 2016

S.No. States No. of drugs samples declared not of standard quality No. of drugs samples declared spurious/ adulterated Approx. value of drug seized (Rs.)
1 Andhra Pradesh 113 90 1614601
2 Arunachal Pradesh 17 2 (1 Surious + 1 misbranded) Nil
3 Assam 21 Nil Nil
4 Bihar*** 3 Nil Nil
5 Goa 8 Nil Nil
6 Gujarat 448 8 0
7 Haryana 38 3 Nil
8 Himachal Pradesh 24 Nil Mostly Govt. Supply
9 Jammu & Kashmir 54 1 2,704,443
10 Karnataka 563 Nil Value of NSQ drug seized Rs. 33,66,850
11 Kerala 152 Nil Nil

12 Madhya Pradesh 24 Nil Nil
13 Maharashtra 351 31 Rs.1,01,58,938/-
14 Manipur Nil Nil Nil
15 Meghalaya 16 Nil Nil
16 Mizoram 7 (1 Sample is Misbranded) Nil Rs. 15 Lacs.
17 Nagaland 1 Nil Nil
18 Orissa* 93 1 641583/- Spurious drugs
19 Punjab 165 37 2,51,06,982/-
20 Rajasthan 208 3 2026.50
21 Sikkim Nil Nil Nil
22 Tamilnadu 478 4 Nil
23 Tripura 16 Nil Nil
24 Uttar Pradesh 782 45 Rs 85,32,071/-
25 West Bengal 24 1 Nil
26 Pondicherry Nil Nil Nil
27 Andaman & Nicobar Nil Nil Nil
28 Chandigarh 5 Nil Rs. 22,976/-
29 Delhi 9 5 10 Lakhs
30 Dadra & Nagar Haveli Nil Nil Nil
31 Daman & Diu Nil Nil Nil
32 Lakshadweep Nil Nil Nil
33 Chattisgarh 12 Nil 2,000
34 Jharkhand 29 Nil -
35 Uttarakhand 17 - -
36 Telangana 25 3 661000/-
Total 3703 234 55313470.5
+
Govt. Supply
(*) = Data as on April 2015 to Feb 2016
(**)= Includes 02 raids with Delhi Police officers
(***)= data as on 1st April 2015-30th Sept. 2015)

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2013-14)
S.No. States Quantity of expired drugs seized Approximate value of drugs seized (In Rs)
1 Andhra Pradesh Nil Nil
2 Arunachal Pradesh Nil Nil
3 Assam Nil Nil
4 Bihar * Nil Nil
5 Goa Nil Nil
6 Gujarat Nil Nil
7 Haryana Nil Nil
8 Himachal Pradesh Nil Nil
9 Jammu & Kashmir 15 Ampoules or various drugs other than Neogest Rs. 4278
10 Karnataka Nil 24
11 Kerala 50 no. of 60 drug items Appr. Rs. 3059
12 Madhya Pradesh Nil Nil
13 Maharashtra N.A N.A
14 Manipur Nil Nil
15 Meghalaya Nil Nil
16 Mizoram Nil Nil
17 Nagaland Nil Nil
18 Orissa 37 4011
19 Punjab 9612 tabs, 03 syrups, 290 caps, 42 ORS Pouch 38,000
20 Rajasthan Nil Nil
21 Sikkim Nil Nil
22 Tamil Nadu List enclosed Rs. 9470
23 Tripura Nil Nil
24 Uttar Pradesh Tablets and capsules of different companies 195000
25 West Bangal Nil Nil
26 Pondicherry Nil Nil
27 Andaman & Nicobar Island Nil Nil
28 Chandigarh Nil Nil
29 Delhi Nil Nil
30 Dadra & Nagar Haveli Nil Nil
31 Daman & Diu Nil Nil
32 Lakshadweep Nil Nil
33 Chattisgarh Nil Nil
34 Jharkhand Nil Rs. 700
35 Uttarakhand On raid further stock of expired drugs not found hence no seizure Nil
36 Telangana Nil Nil

(*) Data received til September 2013
Total 10012 254542

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2014-15)
S.No. States Quantity expired drugs seized Approximate value of drugs seized (In Rs)
1 Andhra Pradesh 20 varieties of drugs 20,000
2 Arunachal Pradesh Nil does not arise
3 Assam Nil Nil
4 Bihar * 557 units 40,000
5 Goa Nil Nil
6 Gujarat Nil Nil
7 Haryana Nil Nil
8 Himachal Pradesh NA NA
9 Jammu & Kashmir 15 Ampoules of various drugs other than Neogest 4278
10 Karnataka â€¦. â€¦.
11 Kerala Nil Nil
12 Madhya Pradesh Nil Nil
13 Maharashtra NA NA
14 Manipur Nil Nil
15 Meghalaya Does not arise Does not arise
16 Mizoram Nil Nil
17 Nagaland Nil Nil
18 Orissa Nil Nil
19 Punjab Data Not Available at HQ 73,264
20 Rajasthan 0 0
21 Sikkim Nil Nil
22 Tamil Nadu NA Nil
23 Tripura Nil 0
24 Uttar Pradesh * 309x 10 Tablets of various brands
38x10 Capsules of various brands
14x5ml LVP& 5x40 Condoms 15000
25 West Bangal NA NA
26 Pondicherry Nil Nil
27 Andaman & Nicobar Island Nil Nil
28 Chandigarh None None
29 Delhi Nil Nil
30 Dadra & Nagar Haveli Nil Nil
31 Daman & Diu * NA NA
32 Lakshadweep Nil Nil
33 Chattisgarh 5 cartoon 30000
34 Jharkhand 1 box & 523 tab Nil
35 Uttarakhand Nil Nil
36 Telangana Nil Nil
(*) Data received til September 2014
Total approx 4600 182542
Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2015-16)
S.No. States Quantity expired drugs seized Approximate value of drugs seized (In Rs)
1 Andhra Pradesh 2 3500/-
2 Arunachal Pradesh Nil Nil
3 Assam Nil Nil
4 Bihar** Nil Nil
5 Goa Nil Nil
6 Gujarat Nil Nil
7 Haryana - Approx. 1,90,000/-
8 Himachal Pradesh Nil Nil
9 Jammu & Kashmir 15 Rolls expired cotton & other expired drugs 5800
10 Karnataka Nil Nil
11 Kerala 7 items of varying quantity Appxo. 3576.54 Rs.
12 Madhya Pradesh Nil Nil
13 Maharashtra Nil Nil
14 Manipur Nil Nil
15 Meghalaya Nil Nil
16 Mizoram Nil Nil
17 Nagaland Nil Nil
18 Orissa* Nil Nil
19 Punjab 5 itmes 41,69,772/-
20 Rajasthan - -
21 Sikkim Nil Nil
22 Tamil Nadu 75 items of varying quantity Rs. 2000000/-
23 Tripura 91 items Not Calculated
24 Uttar Pradesh About 76 Gunny bages of expired medicine 5 lakhs

25 West Bangal Nil Nil
26 Pondicherry Nil Nil
27 Andaman & Nicobar Island Nil Nil
28 Chandigarh Nil Nil
29 Delhi Nil Nil
30 Dadra & Nagar Haveli Nil Nil
31 Daman & Diu Nil Nil
32 Lakshadweep Nil Nil
33 Chhattisgarh 1 items 25000
34 Jharkhand - Approximate 4000
35 Uttarakhand - -
36 Telangana variety of drugs seized 1,17,800/-
Total 272 7019448.54
(*) = Data as on April 2015 to Feb 2016
(**) = Data as on 1st April to 30 th sept. 2015)

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for 1 april to 30 sep 2016)
S.No. States Quantity expired drugs seized Approximate value of drugs seized (In Rs)
1 Andhra Pradesh Nil Nil
2 Arunachal Pradesh Does not arise Does not arise
3 Assam Nil Nil
4 Bihar 51 819034
5 Goa Nil Nil
6 Gujarat Nil Nil
7 Haryana Nil Nil
8 Himachal Pradesh Nil Nil
9 Jammu & Kashmir 1 Item (09 vials of Inj. Caspolungin Acetatae) 112500
10 Karnataka Nil Nil
11 Kerala Nil Nil
12 Madhya Pradesh
13 Maharashtra
14 Manipur Nil Nil
15 Meghalaya Does not arise Does not arise
16 Mizoram Nil Nil
17 Nagaland Nil Nil
18 Orissa Nil Nil
19 Punjab Nil Nil
20 Rajasthan Nil Nil
21 Sikkim Nil Nil
22 Tamil Nadu Nil Nil
23 Tripura Nil Nil
24 Uttar Pradesh Nil Nil
25 West Bangal Nil Nil
26 Pondicherry Nil Nil
27 Andaman & Nicobar Island Nil Nil
28 Chandigarh Nil Nil
29 Delhi Nil Nil
30 Dadra & Nagar Haveli Nil Nil
31 Daman & Diu
32 Lakshadweep Nil Nil
33 Chhattisgarh Nil Nil
34 Jharkhand - approx 3000
35 Uttarakhand Nil Nil
36 Telangana Nil Nil
Total 52 934534

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